In the Application of: PATENT
Tony N. Frudakis Attorney Docket No.: DNA1180-2

Application No.: 10/589,291

Filed: June 4, 2007

Page 6

### **REMARKS**

Claims 1-28 are currently pending, with claims 4, 5, and 14-28 having been withdrawn from further consideration. By the present communication, no claims have been added, claim 6 has been canceled without prejudice, and claims 1, 7, and 9 have been amended to define Applicants invention with greater particularity. Support for the amended claim language may be found throughout the specification and claims as filed. Upon entry of the present amendment, claims 1-3 and 7-13 will be under consideration.

### **Priority**

Applicants respectfully traverse the allegation that the disclosures of PCT/US05/004513, U.S. Serial No. 60/544,788, and U.S. Serial No. 60/548,370 do not teach how to infer an eye color based upon an allele. The Office Action asserts that "[t]here is no teaching which allele is associated with which eye color." (Office Action, page 2). Applicant respectfully submits that since the specification does not specifically define the terms "infer" or "inferring", the Office must apply the broadest accepted meaning of the term. Accepted meanings of the term include, but are not limited to, "to guess; speculate; surmise; to hint; imply; suggest; to draw a conclusion, as by reasoning." Applicants respectfully direct the Examiner's attention to paragraph [0068] of the specification as filed, which is identical to that of PCT/US05/004513, and states,

These results provide a panel of SNPs that can be used alone, or in combination, to draw inferences as to the eye color of an individual providing a nucleic acid sample, and demonstrate how an iris color of a subject can be predicted based on the identification of eye color related SNPs in a nucleic acid sample obtained from the subject.

As such, Applicants submit that one of skill in the art would understand how to *infer* eye color based upon an allele in view of Example 1. Applicants respectfully request that the instant application be accorded at least the priority date of U.S. Serial No. 60/544,788, filed February 13, 2004.

In the Application of: PATENT
Tony N. Frudakis Attorney Docket No.: DNA1180-2

Application No.: 10/589,291

Filed: June 4, 2007

Page 7

## Rejections Under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 1-3 and 6-13 as allegedly failing to comply with the enablement requirement. Specifically, the Office Action indicates that "the specification, while being enabling for a method for detecting the SNP at nucleotide 68 of SEQ ID NO: 3 and nucleotide 171 of SEQ ID NO: 4, does not reasonably provide enablement for a method of inferring natural eye color in a human subject based upon detecting the SNP at nucleotide 68 of SEQ ID NO: 3 and nucleotide 171 of SEQ ID NO: 4.

Without acquiescing the reasoning of the Action and in order to further prosecution of instant application, Applicant has amended claim 1 to recite a method for inferring natural eye color of a human subject from a nucleic acid sample of the subject, comprising identifying in the nucleic acid sample at least one nucleotide occurrence of an eye color related single nucleotide polymorphism (SNP) of an oculocutaneous albinism II (OCA2) gene, and comparing the identified at least one nucleotide occurrence with known nucleotide occurrences of eye color related SNPs associated with known eye colors. Applicant respectfully directs the Examiner's attention to paragraph [0059] of the specification as filed, which describes

The iris color of a subject can be predicted from a nucleic acid sample by determining the genotype of the sample with respect to SNPs as shown in Table 2 (e.g., with one or more of the SNPs of SEQ ID NOS: 1 to 7); comparing the genotype against those for known subjects in a database (i.e., subjects for whom eye color has been associated with nucleotide occurrence(s) of the SNPs; and identifying known subjects whose genotypes match the unknown sample. The iris colors of the known subjects thus provide a guide.

As such, one of skill in the art, in view of the specification as filed, would understand how to infer natural eye color of a human subject by comparing one or more nucleotide occurrences of an eye color related SNP of an oculocutaneous albinism II (OCA2) gene with a panel of SNPs from subjects of known eye color.

The Office Action further alleges that "[t]he specification teaches that iris colors of 'unknown' samples based on genotypes of 35 SNPs provided a blind classification accuracy of 97% when an exact match existed across all genotypes in

In the Application of:

Tony N. Frudakis

Attorney Docket No.: DNA1180-2

Application No.: 10/589,291 Filed: June 4, 2007

Page 8

Table 2. This seems to state that iris color could be inferred correctly 97% of the time if ALL 35 SNPs were correct."

As discussed above, the instant application provides methods of interring eye color/shade (see, e.g., paragraph [0058] of the specification as filed). Table 2 of the specification as filed denotes that "'lighter' indicates blue or green eyes; 'darker' indicates brown or hazel eyes." Thus, while it may have been observed that when an exact match existed across all 35 SNPs, the inference was 97% accurate, one of skill in the art, in view of Example 1 and Tables 2 and 3, may infer with a reasonable sense of accuracy the natural eye color/shade of the subject. Withdrawal of the rejection is respectfully requested.

## Rejections Under 35 U.S.C. §112, Second Paragraph

Applicants respectfully traverse the rejection of claims 1-3 and 6-13 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Specifically, the Office Action alleges that the final process step is drawn to identifying SNPs, rather than inferring natural eye color. Without acquiescing the reasoning of the Action and in order to further prosecution of instant application, Applicant has amended claim 1 to include the step of comparing the identified at least one nucleotide occurrence with known nucleotide occurrences of eye color related SNPs associated with known eye colors. Support for the amended claim language may be found at, for example, at paragraph [0040]-[0042], [0057], and [0059] of the specification as filed. Withdrawal of the rejection is respectfully requested.

In the Application of: Tony N. Frudakis

Application No.: 10/589,291

Filed: June 4, 2007

Page 9

# CONCLUSION

Attorney Docket No.: DNA1180-2

In view of the foregoing amendments and the remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this case.

The Commissioner is hereby authorized to charge \$245.00 as payment for the Petition for the Two-Month Extension of Time to Deposit Account No. 07-1896. No additional fee is believed due. If any additional fee is due, the Commissioner is hereby authorized to charge any fees required by this submission, or make any credits or overpayments, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

Date: May 10, 2010

Lisa A. Haile, J.D., Ph.D. Registration No.: 38,347

Telephone: (858) 677-1456 Facsimile: (858) 677-1465

DLA PIPER LLP (US) 4365 Executive Drive, Suite 1100 San Diego, California 92121-2133 USPTO Customer No.: 28213